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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Neurological Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Neurological Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 16, 1999, 11 a.m. to 6 p.m., and September 17, 1999, 8:30 a.m. to 3:30 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: Janet L. Scudiero, Center for Devices and Radiological Health (CDRH) (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1184, ext. 176, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12513. Please call the Information Line or access the World Wide Web at "http://www.fda.gov/cdrh/upadvmtg.html" for up-to-date information on this meeting.

Agenda: On September 16, 1999, the committee will discuss and make recommendations on: (1) The draft guidance entitled "Guidance Document for Dura Substitute Devices," and (2) the classification of processed human dura mater. FDA notes that the guidance entitled "Guidance for the Preparation of a Premarket Notification Application for Processed Human Dura Mater,"

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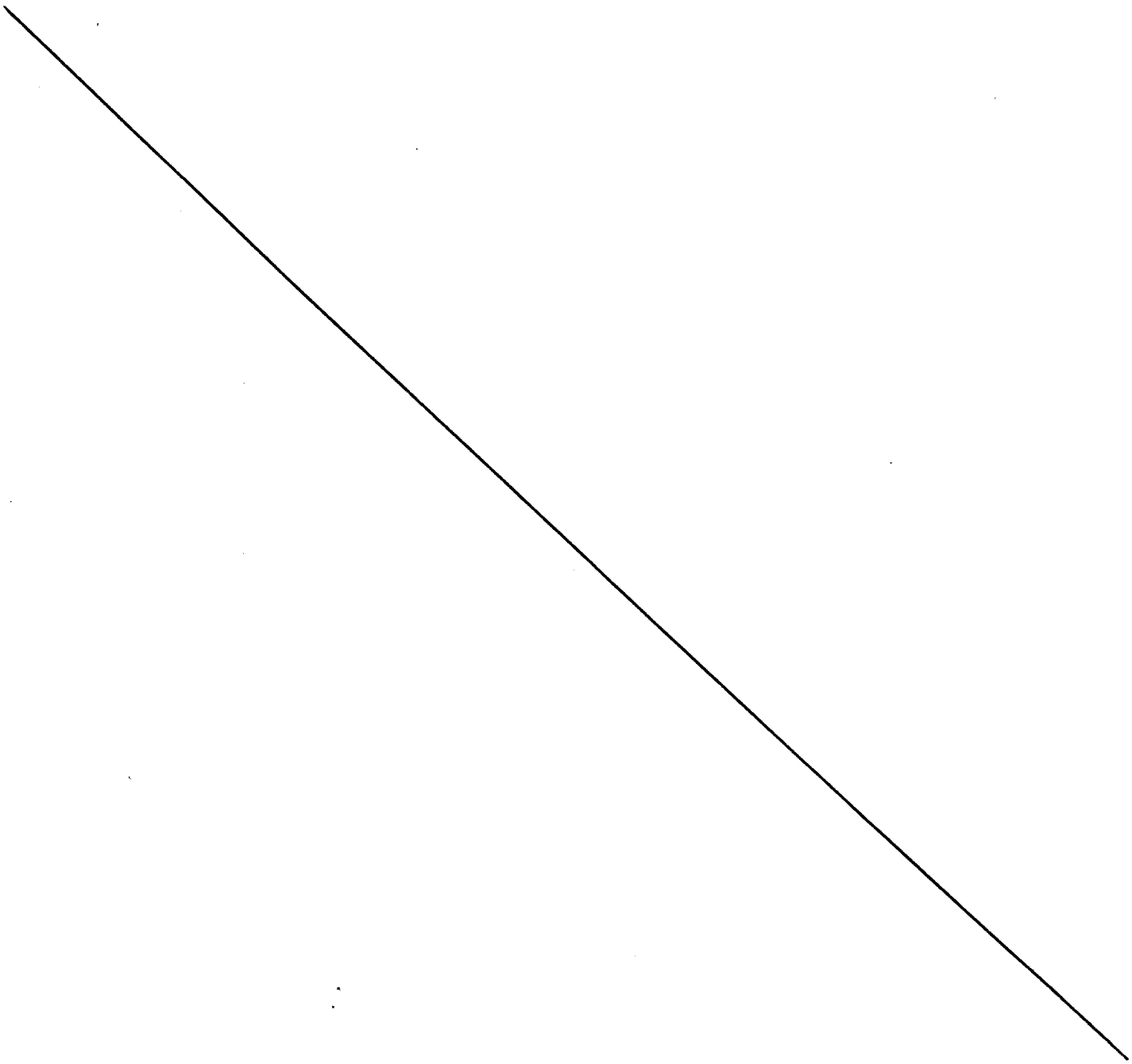
which related to the classification of processed human dura mater, became effective on July 31, 1999.

On September 17, 1999, the committee will discuss and make recommendations on: (1) The draft guidance entitled ''Guidance Document for Neurological Embolization Devices,'' and (2) the reclassification of the totally implanted spinal cord stimulator. Single copies of the guidance and the draft guidances are available to the public by calling 1–800–899–0381 or 301–827–0111 and requesting CDRH Facts-on-Demand by assigned document number, or the documents may be obtained on the Internet at the CDRH website as follows: ''Guidance Document for Dura Substitute Devices,'' Facts-on-Demand document number 1152, or ''http://www.fda.gov/cdrh/ode/1152.pdf''; ''Guidance for the Preparation of a Premarket Notification Application for Processed Human Dura Mater,'' Facts-on-Demand document number 054, or ''http://www.fda.gov/cdrh/ode/054.pdf''; and ''Guidance Document for Neurological Embolization Devices,'' Facts-on-Demand document number 1151, or ''http://www.fda.gov/cdrh/ode/1151.pdf''.

Procedure: On September 16, 1999, from 11 a.m. to 6 p.m., and on September 17, 1999, from 8:30 a.m. to 3:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 8, 1999. Oral presentations from the public will be scheduled on September 16, 1999, between approximately 12 noon and 12:30 p.m. for the discussion of the draft guidance entitled ''Guidance Document for Dura Substitute Devices'' and between approximately 3:45 p.m. and 4:15 p.m. and 5 p.m. and 5:30 p.m. for the classification of processed human dura mater. On September 17, 1999, oral presentations from the public will be scheduled between approximately 9:45 a.m. and 10:15 a.m. for the discussion of the draft guidance entitled ''Guidance Document for Neurological Embolization Devices'' and between approximately 12:15 p.m. and 12:45 p.m. and 2:30 p.m. and 3 p.m. for the reclassification of the totally implanted spinal cord stimulator. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September

8, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On September 17, 1999, from 8 a.m. to 8:30 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information regarding pending and future FDA issues. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).



Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 25, 1999

Linda A. Suydam
Senior Associate Commissioner

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

[FR Doc. 99–???? Filed ??–??–99; 8:45 am]

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